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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,739	08/21/2003	Shaher A. Ahmad	073275.0146	9156

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EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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04/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/645,739	Applicant(s) SHAHER, AHMED	
	Examiner JAMES L. SWIGER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-51 is/are pending in the application.
- 4a) Of the above claim(s) 17-29 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-16, 30-32, 36-42 and 45-51 is/are rejected.
- 7) ☒ Claim(s) 43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/21/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Applicant, in Fig. 1, shows a "delta" but does not define this delta in the specification. It appears that applicant used "gamma" to define the trailing angle, however it is not clear whether this is supposed to be the same thing as the delta.

. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

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Claims 46, 15, and 42 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. Applicant has positively claimed "the surface of the bone" in lines 14-17 of claim 1, lines 19-22 of claim 42, and lines 3-5 of claim 46.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 47 and 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what applicant has defined as the trailing angle in claim 47 and 51. Insufficient information in the specification has been provided.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-3, 5, 12, 14-16, 30, 32, 36, 38-41, 45-46, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. (US patent 5,417,692), hereafter "Goble."

Goble discloses a bone anchor comprising a self drilling screw portion (see Fig. 10; 11a; the distal portion with a conically shaped tip end is shown at approximately 26; it is also noted that this screw portion may also be considered self tapping), wherein the screw portion is configured to penetrate bone, a retention thread (25) that extends at least part of the length of the screw portion, a tip (at the distal end as noted above) that is at a first end, a protrusion (approx. 22, Fig. 10), that is adjacent a second end of the screw portion, which is opposite of the first screw portion, wherein the protrusion further has external sides (22) forming a shape (see also view in Fig. 7), and a rounded interior surface that encloses a recess (see cross section in Fig. 10, surrounding 15) which is capable of receiving a portion or something, or also a component, wherein this inner surface is considered rounded and it also has a single, continuous thread extending the major of the length of the recess (thread: 21; note the recess continues down further sans threads). This receiving portion or protrusion recess is configured to rotatably retain a threaded component at least partially in this recess. This protrusion also has a maximum width that is less than a maximum diameter of the screw portion such that a shoulder is formed (shoulder is on the 2nd end side of thread cross section 16, as shown in Fig. 10), where the protrusion meets the second end of the screw portion and this shoulder is considered continuous around this portion of the screw. The screw

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further has at least one cutting flute (slice down the screw), and has a hexagonal shape (see fig. 7).

Alternatively, Goble also discloses a driver (see fig. 3) for inserting a bone anchor into bone comprising a tip portion (bottom face of insertion tool 23) with a first diameter (surrounding #24), having a driver edge, and an external surface (outward facing portion encircling the tip portion). The driver also has a plurality of internal surfaces forming a shape (hexagonal, for example, 24). It is noted that this driver recess is fully capable and configured to retain an insert positioned within a protrusion recess of the bone anchor during insertion, wherein this bone anchor for insertion may be inserted. The tip portion forms around the head of a bone anchor (17/22). Additionally Goble teaches that the tip portion positions around a protrusion of a bone anchor when this is used to insert a bone anchor into bone. This contacts a shoulder of a bone anchor. The driver also has a tip with a first diameter (as shown) and also a second portion adjacent to this first portion that has a second diameter. A rim is formed where the first and second diameters meet. The distance between the driver edge and the rim is also approximately the length of the protrusion of the bone screw, as this would enable a full grabbing of the bone screw in use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble in view of Lee et al. (US Publication 2004/0030237). Goble discloses the claimed invention except for wherein the threaded component comprises a fiducial marker component. Lee et al. discloses a fiducial component (106) that may be used in a threaded protrusion recess. Use of this allows surgeons to track, image, or guide additional tools during a surgical procedure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Goble having at least a fiducial marker component that can be used in a threaded protrusion recess in view of Lee et al. to have improved guidance and/or visibility during surgery.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goble in view of Niznick (US patent 5,989,028). Goble discloses the claimed invention except for first and second cutting flutes that are spaced 180 degrees apart. Niznick discloses a bone anchor that has notches/holes 42/43 that function as flutes that are approximately 180 degrees apart. Having fluted portions separated by this amount can help with making the bone cuts via the tapping and installation more balanced. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Goble having at least flutes that are separated by approximately 180 in view of Niznick to have a more balanced cutting profile when installing the screw.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. Goble discloses the claimed invention except for a shape having various

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forms such as a cruciform, D-shape, or approximate square. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the shape having any of the above forms, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of inserting the bone anchor into bone. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 10, and 50-51 rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. Goble discloses the claimed invention except for the bone anchor having specific lengths or angles. It would have been an obvious matter of design choice to construct the device of Goble having the various length or angles, such as a length of 0.2 inches or a thread angle, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goble in view of Friedman et al. (US Patent 5,209,659). Goble discloses the claimed invention except for an entrance with a chamfered interior surface. Friedman et al. discloses a chamfered interior surface (126/128) which assists with improved fitting of the inserted component, and also helps to guide the component into place in the even the surgeon does not perfectly align the devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Goble

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having at least a chamfered interior surface in view of Friedman to have an improved entryway into the device for the insert and assist the surgeon with installation.

Allowable Subject Matter

Claims 43-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 47 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

Applicant's arguments with respect to claims 1-12, 14-16, 30-32, 36-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775